

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 13 of 21*

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REMARKS

The claims of the present application are directed to an apparatus for aspirating, irrigating and/or cleansing wounds and to a method of treating wounds using the claimed apparatus. Prior to this Response, Claims 1-10 were pending. In this Response, Applicants amend Claims 1-8, cancel Claim 9, and add new Claims 11-33. Claims 1-9 and 10-33 will be pending upon entry of the amendments.

Support for the Amendments to the Claims and the New Claims

Support for the claim amendments and the new claims is found throughout the application, as filed. Currently amended Claims 1-8 and new Claims 15-21 are based on Claims 1-8 as previously pending. The amendments clarify the claims and correct informalities and typographical errors. Additional support for claim amendments is found throughout the present application, as filed. In particular, please see Figures 1 and 27 and paragraphs 0432-0454, 0501-0524 and 0641-0643 of the publication of the present application as U.S. Patent Application Publication Number 2006/0155260 ("publication"). Support for the new Claims 11-14 is found throughout the present application, as filed. For example, support for new Claims 11-14 is found, in paragraphs 0507, 0516, 0520, 0052, 0639, 0642 and 0645, and Figures 1 and 27 (see, in particular, item 17 in Figure 1 and items 913-915 in Figure 27) of the publication. New Claim 22 is based on Claim 1 as previously pending and further supported, for example, in paragraph 0272-0279 and 0235. New Claims 23-28 are supported, for example, in paragraph 0052 and Figure 27 (see, in particular, item 914). New Claims 29-30 are supported, for example, in paragraphs 0235-0248 of the publication. New Claim 31 is supported, for example, in paragraphs 0507, 0516 and 0520 of the publication. New Claim 32 is based on Claim 6 as previously pending. New Claim 33 is based on previously presented Claim 10. Accordingly, the claim amendments and the new claims do not introduce any new matter.

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 14 of 21*

Amendments to the Specification

Applicants amend the specification to correct the informalities. The amendments to the specification do not add any new matter.

Claim Objections

The Office Action objects to Claims 6-8, asserting informalities in Markush-type claims. See page 2 of the Office Action. Applicants amend Claims 6-8 to recite Markush groups as provided in MPEP 2173.05(h). Applicants assert that the amendments overcome the claim objections and request their withdrawal.

Claim Rejections under 35 U.S.C. §112, Second Paragraph, for Indefiniteness

The Office Action rejects Claims 1-10 under 35 U.S.C. §112, second paragraph, as indefinite. Applicants assert that the claim amendments overcome the rejections.

Claim 1

The Office Action asserts that, in sections (b)-(d) of Claim 1, the claim recites several limitations that are listed as optional or necessary, rendering the scope of the claim unclear. See page 2 of the Office Action. Applicants amend Claim 1 to delete the rejected language and to clarify the claim.

The Office Action asserts that the term “the wound facing face” in Claim 1 is unclear and lacks an antecedent basis in the claim. See page 2 of the Office Action, the last two paragraphs. Applicants amend Claim 1 to clarify, in part (a)(i), that “a wound facing face” is a part of “a conformable wound dressing,” and to provide a proper antecedent basis for the subsequent instances of the term “the wound facing face.”

Applicants assert that the foregoing amendments clarify the scope of Claim 1 and render it definite. Accordingly, Applicants assert that the amendments overcome the rejection of Claim 1 under 35 U.S.C. §112, second paragraph.

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 15 of 21*

Claims 2-5

The Office Action asserts that Claims 2-5 each recite the limitation "the circulating fluid," which lacks antecedent basis. See page 3 of the Office Action, the first four paragraphs. Applicants amend Claims 2-5 to delete the language "the circulating fluid." Applicants assert that the amendments clarify the scope of Claims 2-5 and render them definite. Accordingly, Applicants assert that the amendments overcome the rejections of Claims 2-5 under 35 U.S.C. §112, second paragraph.

In view of the foregoing, Applicants request withdrawal of the rejections of Claims 1-10 under 35 U.S.C. §112, second paragraph, as indefinite.

Claim Rejections under 35 U.S.C. §102(b)

The Office Action rejects Claims 1-3, 6-8 and 9-10 under 35 U.S.C. §102(b) in light of International Application Publication No. WO 84/01904 ("*Swanbeck*"). Applicants cancel Claim 9, thereby rendering its rejection moot. Anticipation requires the cited reference to teach each and every element of the claim. See MPEP 2131.01. *Swanbeck* does not teach at least two elements recited in Claims 1-3, 6-8, 10, or any other pending claims, namely, (1) a conformable wound dressing, and (2) a fluid reservoir switchably connected to an integer of the flowpath via means for flow switching in the flowpath between supply of a fluid from the reservoir or recirculation of fluid in the flowpath, or a combination of the supply or the recirculation. At least in view of the foregoing, *Swanbeck* fails to anticipate pending claims.

Swanbeck Teaches a Device for Rinsing and Treating Wounds and Infected Skin Portions

Swanbeck teaches a device for rinsing and treating wounds and infected skin portions. A copy of Figure 1 from *Swanbeck* is shown below for easy reference. In reference to Figure 1, above, *Swanbeck* discloses a device comprising a suction cup (10) placed over the area to be treated, and a vessel with a treatment solution (15) communicating with the interior of the suction cup. The device in *Swanbeck* also may

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 16 of 21*

comprise a pump (13) to circulate the solution and a sterilizing filter (15). See, for example, *Swanbeck*, Abstract, page 1, last paragraph through page 4, first full paragraph.

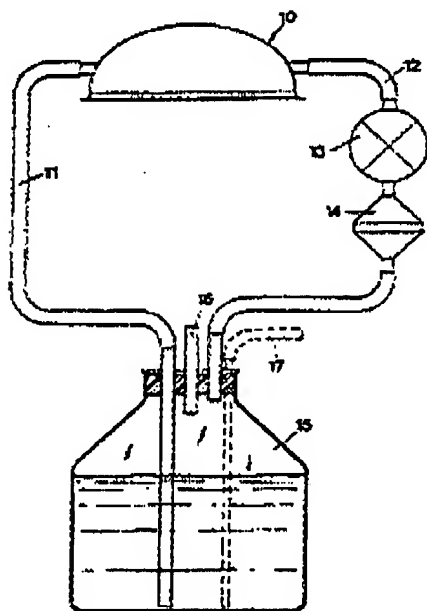


Figure 1 of *Swanbeck*

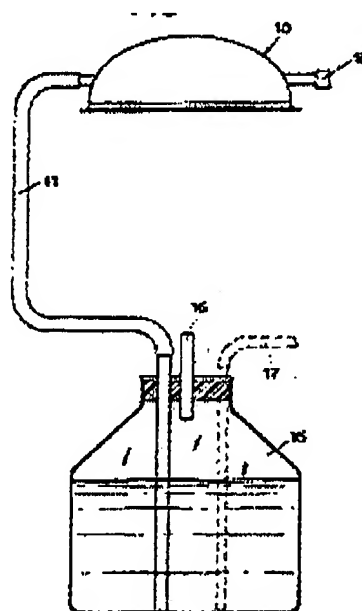


Figure 2 of *Swanbeck*

The device forms a closed liquid system for recirculation of the treatment solution over the wound, with the purpose of providing nutritives, drugs, etc., to the wound, to wash away waste products from the wound, and, optionally, to continuously sterilize the treatment solution or to oxygenate the wound. See *Swanbeck*, page 4, fourth full paragraph. The second device disclosed in *Swanbeck* and depicted in Figure 2, also included in this Response for easy reference, does not comprise a pump and does not provide for circulation in the liquid system besides convection within the cup. See, for example, *Swanbeck*, page 5, first paragraph.

The Dressing in *Swanbeck* Is a Suction Cup, Not a Conformable Wound Dressing

Swanbeck does not teach at least one element recited in Claims 1-3, 6-8, 10, or any other pending claims, namely, a conformable wound dressing. The dressing in

U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 17 of 21

Swanbeck is a suction cup. *Swanbeck* explains, for example, on page 2, that the suction cup is a cup-shaped member, and "... vessel and cup-shaped member by way of ... tube connection form a closed liquid system thereby providing a uniform low pressure within the cup-shaped member, which may be regulated by the level difference between the cup-shaped member and the vessel." *Swanbeck* depicts a cup-shaped dressing in both figures in the application. See *Swanbeck*, element (10) in Figures 1 and 2. The low pressure in the suction cup prevents leaking from the cup. See *Swanbeck*, page 3, third paragraph. Accordingly, the suction cup in *Swanbeck* necessarily attaches to the area to be treated through suction, or negative pressure, and negative pressure is therefore necessarily applied to the treated area.

In contrast, the dressing recited in all pending claims, including rejected Claims 1-3, 6-8 and 10, is conformable, and its "particular advantage is the tendency of the wound dressing to conform to the shape of the bodily part to which it is applied." See paragraph 0082 of the publication. *Swanbeck* does not teach or suggest a dressing that conforms to the application area.

Furthermore, *Swanbeck* does not teach or suggest any attachment of the cup dressing other than suction. In contrast, the dressing recited in the claims, unlike the suction-cup dressing disclosed in *Swanbeck*, does not necessarily attach through suction, it may be attached to the periphery of the wound by using an adhesive. See, for example, paragraphs 0100-0102 of the publication. Therefore, the use of the conformable dressing recited in the claims does not necessitate application of the negative pressure to the wound, unlike the use of the suction cup dressing in *Swanbeck*.

At least for the above reasons, *Swanbeck* fails to teach all elements of the apparatus, as recited in Claims 1-3, 6-8, 10, or any other pending claims. Applicants respectfully request that the rejection based on *Swanbeck* be reconsidered and withdrawn.

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 18 of 21*

Swanbeck Fails to Teach a Fluid Reservoir Switchably Connected to the Flowpath

Swanbeck does not teach at least one more element recited in Claims 1-3, 6-8, 10, or any other pending claims, namely, a fluid reservoir switchably connected to the flowpath via means for flow switching in the flowpath between supply of a fluid from the fluid reservoir or recirculation of the fluid in the flowpath, or a combination of the supply and the recirculation.

The systems disclosed in *Swanbeck* are: as shown in Figure 1, a closed recirculation system for a treatment solution supplied from a vessel (15); and, as shown in Figure 2, a closed convection system for application of the treatment solution from a vessel (15). Both systems disclosed in *Swanbeck*, once equilibrated, require continuous application of the same volume of the treatment solution, and only the exchange of the total volume is possible as discussed on page 4, bottom. In fact, continuous application of a set volume of a treatment solution is the whole purpose of the systems disclosed in *Swanbeck*. Additionally, as discussed in the previous section, the systems in *Swanbeck* require negative pressure at the treatment site during operation.

In contrast to *Swanbeck*, pending claims describe an embodiment of Applicant's apparatus that allows continuous delivery of additional irrigant to the wound or recirculation of the fluid in the system, or any combination of recirculation and delivery, as needed or desired, based on various factors, such as the exuding state of the wound. Additionally, by balancing fluid recirculation and irrigant delivery in the system, the apparatus recited in the claims allows for application of positive or negative pressure to the wound bed, as needed or desired. For a more detailed explanation, see, for example, paragraphs 0442-0464 of the publication. *Swanbeck* fails to teach an irrigation system comprising an element that allows for delivery of additional fluid into the system only as needed or desired, fails to teach adjustment of a balance between recirculation or fluid delivery in the system, and fails to teach delivery of positive or negative pressure to the wound site.

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 19 of 21*

At least for the above reasons, *Swanbeck* fails to teach all elements of the apparatus, as recited in Claims 1-3, 6-8, 10, or any other pending claims. Applicants respectfully request that the rejection based on *Swanbeck* be reconsidered and withdrawn.

Swanbeck Fails to Disclose a Means for Fluid Cleansing that is a Two-Phase System

The Office Action asserts on page 4, last paragraph, that, *Swanbeck* disclosed on page 3, lines 4-6, a means for fluid cleansing that is a two-phase system, as recited in Claim 3. Applicants disagree. On page 3, lines 4-6, *Swanbeck* discloses a tube (element (17) in Figure 1) that is bubbled into the solution "to ensure oxygenation of the wound to be treated." That is, *Swanbeck* discloses a system for delivery of oxygen to the wound, not a two-phase cleansing system. *Swanbeck* suggests using an optional sterilizing filter on page 3, bottom, but fails to teach or suggest a two-phase cleansing system anywhere in the disclosure. At least for this reason, *Swanbeck* fails to teach all elements of Claim 3. Applicants respectfully request that the rejection of Claim 3 or any of the claims dependent thereon based on *Swanbeck* be reconsidered and withdrawn for at least this reason.

Miscellaneous

The Office Action states on page 5 that language in section (b)-(d) of Claim 1 is stated as optional and therefore is not considered as a limitation of the claimed invention. Applicants' amendments clarify that Claim 1 recites elements (b) and (c). Element (d) is recited in a new independent Claim 15 and its dependent Claims 16-21. Accordingly, Applicants asserts that elements (b) and (c) in currently pending Claim 1 and elements (b)-(d) in currently pending Claim 15 are limitation of the respective claims.

The Office Action states on page 5: "Regarding claims 6-8, see page 4, 2nd paragraph." Applicants respectfully respect clarification. On page 4, 2nd paragraph, *Swanbeck* provides a list of "active ingredients in the solution to be circulated." In the cited passage, *Swanbeck* fails to teach any of the elements of the means for fluid cleansing recited in the dependent Claims 6-8.

U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 20 of 21

Claim Rejections under 35 U.S.C. §103(a)

The Office Action rejects Claims 4-5 as obvious under 35 U.S.C. §103(a) in view of *Swanbeck*. To establish a *prima facie* case of obviousness, the reference must teach or suggest all the claim limitations, and the teaching or suggestion to make the claimed combination must be found in the prior art. See MPEP 2142. Claims 4-5 are dependent on Claim 3, which, in turn, is dependent on Claim 1. Accordingly, Claims 4-5 include all limitations of Claims 1 and 3. As discussed in the previous section, *Swanbeck* fails to teach or suggest at least two limitations recited in Claim 1, (1) a conformable wound dressing and (2) a fluid reservoir switchably connected to the flowpath via means for flow switching in the flowpath between supply of a fluid from the fluid reservoir or recirculation of the fluid in the flowpath, or a combination of the supply and the recirculation. *Swanbeck* also fails to teach or suggest at least one limitation recited in Claim 3, (3) a means for fluid cleansing that is a two-phase system. Accordingly, *Swanbeck* fails to teach or suggest at least three limitations recited in Claims 4-5. Further, there is no suggestion or motivation in *Swanbeck* to modify the reference to arrive at these claim limitations. Accordingly, *Swanbeck* fails to render Claims 4-5 *prima facie* obvious at least for the foregoing reasons. Applicants request withdrawal of the rejection of Claims 4-5 as obvious under 35 U.S.C. §103(a) in view of *Swanbeck*.

*U.S. Patent Application Serial No. 10/533,275
Amendment and Response to the First Office Action
Page 21 of 21*

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CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed January 16, 2007. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues that can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies that may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,



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